

**REMARKS**

Claims 1, 4-6, 9-19, 21-26, 28-33, 35-38, 40, and 42-50 are pending in the application. Claim 50 has been amended to correct a grammatical error as suggested by the Examiner. Claims 29 and 48 have been amended. Support for the claim amendments may be found throughout the specification, including the claims as originally filed. No new matter has been added.

Support for the amendment to claims 29 and 48 may be found on page 18 lines 19-26, page 19 lines 1-17 and page 56 lines 28-30.

Amendment of claims should in no way be construed as an acquiescence to any of the Examiner's rejections. The amendments to the claims are being made solely to expedite prosecution of the present application. Applicants reserve the right to further prosecute claims drawn to all subject matter disclosed in the instant patent application or in a continuation hereof. The Examiner's remarks in the last Office Action are addressed below. It is believed that the pending claims, taken in light of the remarks made herein, meet all criteria for patentability.

## CLAIM OBJECTIONS

The Examiner has objected to claim 50 because “the phrase “providing the said cancer cell” is not grammatically correct.” Applicants have amended the claim in accordance with the Examiner’s helpful suggestion. Applicants respectfully submit that the objection is now moot and should be withdrawn.

## CLAIM REJECTIONS

### *Rejection of claim 28 under 35 U.S.C. §112, second paragraph*

The Examiner has rejected claim 28 under 35 U.S.C. §112, second paragraph allegedly as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection.

Specifically, the Examiner has pointed out that

“[c]laim 28 is vague and indefinite in that the metes and bounds of the term ‘derived from’ are unclear. It is unclear the nature and number of steps required to obtain a ‘derivative’ of the delivery agent.” The Examiner further states that “[t]he term implies a number of different steps that may or may not result in a change in the functional characteristics of the delivery agent from the source that it is ‘derived from’. It would be remedial to amend the claim language to use the term --obtained from--, which implies a more direct method of acquiring **human cells**.” (Office Action, page 3; emphasis added).

Applicants respectfully traverse this rejection.

Applicants submit that claim 28 recites “wherein said viral vector, said virus and said viral particle are derived from one of the following: recombinant retrovirus, adenovirus, adeno-associated virus, or herpes simplex virus-1.” This claim does not imply any methods of acquiring **human cells** as suggested by the Examiner. Further, support for the term “derived from” may be found in the specification from page 28, line 1 to page 31, line 5. Attention is directed to page 29, lines 24-30 and page 31, lines 1-5. The term “derived from” is a customary term of art, and refers to viral vectors constructed using any of the known techniques discussed at pages 28-31. The term is intended to and should be understood to embrace vectors wherein

functional characteristics of the delivery agent are manipulated relative to the characteristics of the source material. For example, Applicants teach at page 29, lines 25-28, that an adeno virus vector can be altered by inactivating its ability to engage in a normal lytic viral life cycle. Applicants submit that the examples in the specification provide sufficient guidance to enable one skilled in the art to utilize a viral vector derived from the viruses of claim 28.

As the Applicants have taught how to make and use the invention in claim 28, Applicants submit that they have fully enabled the scope of this claim. Applicants respectfully request reconsideration and withdrawal of all rejections under 35 U.S.C. §112, second paragraph.

**Rejection of claims 29 and 48 under 35 U.S.C. §102(b) over Mathiowitz et al.**

The Examiner has rejected claims 29 and 48 under 35 U.S.C. §102(b) as allegedly being anticipated by Mathiowitz et al. (WO 95/24929). The Examiner relies on Mathiowitz et al. as teaching a

“polymeric gene delivery system comprising a gene under a control of an appropriate promoter for expression in a particular cell type being encapsulated or dispersed within a biocompatible polymeric matrix, wherein the matrix is in the form of a microsphere and wherein the gene is able to diffuse out of the matrix over an extended period of time (page 5, lines 15-30). Mathiowitz et al. also teach that the gene can be incorporated directly into the polymer, or first incorporated into another material enhancing penetration of the DNA through the cell wall, such as liposomes or surfactant (page 5, lines 30-35). The gene can be delivered in the form of viral vectors ... Among various microspheres’ preparations, Mathiowitz et al. teach that carboxymethylcellulose microspheres are prepared by dissolving the polymer in an acid solution and precipitating the microspheres with lead ions....” (Office Action, pages 3-4).

The Examiner further asserts that “[i]t is apparent that the carboxymethylcellulose microspheres of Mathiowitz et al. are simple coacervate microspheres which are defined as a single kind of hydrophilic material that is caused to emerge from solution by the addition of a phase-separation-inducing substance ...and that lead ions or lead nitrate ions would inherently crosslink the carboxymethylcellulose microspheres.” (Office Action, page 4).

Claims 29 and 48 have been amended herein to specify that the recited microspheres comprise a polycation and a polyanion. A claim is anticipated only if each and every element of

the claim is found in a single prior art reference. Mathiowitz et al. does not disclose “a coacervate microsphere comprising a polycation and a polyanion” as recited in pending claims. Because Mathiowitz et al. does not disclose each and every element of the claims, the Applicants respectfully submit that this reference does not anticipate amended claims 29 and 48. Accordingly, Applicants respectfully request the withdrawal of the rejection of claims 29 and 48 under 35 U.S.C. §102(b).

## CONCLUSION

Applicants have, by way of the amendments and remarks made herein, obviated or rendered moot each of the objection and rejections set forth in the May 18, 2004 Office Action. Applicants respectfully urge that the amended application is in condition for allowance. Favorable reconsideration and early allowance thereof are respectfully solicited.

If the Examiner has any questions, or believes that a teleconference would facilitate the further prosecution of this application, the Examiner is urged to contact the undersigned at the telephone number listed below.

Respectfully submitted,  
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